

## § 12.93

(2) To identify the most appropriate techniques for developing evidence on issues in controversy and the manner and sequence in which they will be used, including, where oral examination is to be conducted, the sequence in which witnesses will be produced for, and the time and place of, oral examination. The presiding officer may consider—

(i) Submission of narrative statements of position on factual issues in controversy;

(ii) Submission of evidence or identification of previously submitted evidence to support such statements, such as affidavits, verified statements of fact, data, studies, and reports;

(iii) Exchange of written interrogatories directed to particular witnesses;

(iv) Written requests for the production of additional documentation, data, or other relevant information;

(v) Submission of written questions to be asked by the presiding officer of a specific witness; and

(vi) Identification of facts for which oral examination and/or cross-examination is appropriate.

(3) To group participants with substantially like interests for presenting evidence, making motions and objections, including motions for summary decision, filing briefs, and presenting oral argument.

(4) To hear and rule on objections to admitting into evidence information submitted under § 12.85.

(5) To obtain stipulations and admissions of facts.

(6) To take other action that may expedite the hearing.

(c) The presiding officer shall issue, orally or in writing, a prehearing order reciting the actions taken at the prehearing conference and setting forth the schedule for the hearing. The order will control the subsequent course of the hearing unless modified by the presiding officer for good cause.

### § 12.93 Summary decisions.

(a) After the hearing commences, a participant may move, with or without supporting affidavits, for a summary decision on any issue in the hearing. Any other participant may, within 10 days after service of the motion, which

## 21 CFR Ch. I (4–1–02 Edition)

time may be extended for an additional 10 days for good cause, serve opposing affidavits or countermove for summary decision. The presiding officer may set the matter for argument and call for the submission of briefs.

(b) The presiding officer will grant the motion if the objections, requests for hearing, other pleadings, affidavits, and other material filed in connection with the hearing, or matters officially noticed, show that there is no genuine issue as to any material fact and that a participant is entitled to summary decision.

(c) Affidavits should set forth facts that would be admissible in evidence and show affirmatively that the affiant is competent to testify to the matters stated. When a properly supported motion for summary decision is made, a participant opposing the motion may not rest upon mere allegations or denials or general descriptions of positions and contentions; affidavits or other responses must set forth specific facts showing that there is a genuine issue of fact for the hearing.

(d) Should it appear from the affidavits of a participant opposing the motion that for sound reasons stated, facts essential to justify the opposition cannot be presented by affidavit, the presiding officer may deny the motion for summary decision, order a continuance to permit affidavits or additional evidence to be obtained, or issue other just order.

(e) If on motion under this section a summary decision is not rendered upon the whole case or for all the relief asked, and evidentiary facts need to be developed, the presiding officer will issue an order specifying the facts that appear without substantial controversy and directing further evidentiary proceedings. The facts so specified will be deemed established.

(f) A participant may obtain interlocutory review by the Commissioner of a summary decision of the presiding officer.

### § 12.94 Receipt of evidence.

(a) A hearing consists of the development of evidence and the resolution of factual issues as set forth in this subpart and in the prehearing order.